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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,043	08/01/2006	Bala Rathinasabapathi	10457-055US	1007

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ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,043	RATHINASABAPATHI ET AL.	
	Examiner	Art Unit	
	Phuong T. Bui	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1 The Office acknowledges the receipt of Applicant's restriction election filed October 16, 2008. Applicant elects Group II, claims 15-35 without traverse. Claims 1-35 are pending. Claims 1-14 are withdrawn from examination. Claims 15-35 are examined in the instant application. This restriction is made FINAL.

SEQ ID NO:1 encoding SEQ ID NO:2 was first disclosed in PCT/US05/009047. Provisional Application No. 60/554041 refers to SEQ ID NOs:1 and 2, however, no sequence listing was provided.

Applicant is required to update the first line of the specification with priority benefit information.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449, filed October 31, 2007 is attached to the instant Office action.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted August 1, 2006 are informal drawings. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

4. Claims 25 and 34 are objected to because of the following informality: "from" is misspelled.

Sequence Listing

5. All sequences in the specification must be identified by SEQ ID NO. See p. 16, for example.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 18-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specification discloses aspartate decarboxylase, but the claims recite aspartate carboxylase. It is unclear what is being claimed. For examination purpose, the Office is interpreting aspartate carboxylase in the claims as aspartate decarboxylase.

In claim 15, since a single nucleic acid cannot encode an aspartate carboxylase, it is suggested Applicant insert "sequence" after "nucleic acid". Subsequent recitations of "nucleic acid" are also rejected. Further, it is suggested "wherein said nucleic acid sequence is expressed" also be inserted, since claims 16-20 refer to properties which transformation alone cannot achieve. See also claim 29.

In claims 16-20, "increased" is a relative term lacking a comparative basis.

In claims 18-20, "plants" lack antecedence.

In claim 22, it is suggested "a" be amended to "the" because there is only one nucleic acid sequence which has SEQ ID NO:1. See also claim 31.

In claims 23 and 24, it is suggested "identical" be amended to "having ___% sequence identity" because it is unclear how the sequences are being compared, either by structure or function. See also claims 32 and 33.

In claims 25 and 34, it is suggested "full length" be inserted before "complement" for clarification, as "complement" reads on a single base.

In claims 26, 27 and 35, it is suggested "a homology of at least 80%" be amended to "at least 80% sequence identity" because it is unclear whether "homology" is refers to evolutionary lineage or sequence similarity.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 15-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1 or a sequence encoding SEQ ID NO:2, does not reasonably provide enablement for the generic recitation of aspartate decarboxylase or less than 100% sequence identity to SEQ ID NO:1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims reciting the generic recitation of aspartate decarboxylase are not enabled because they encompass both naturally occurring and synthetic sequences, known and yet to be discovered sequences, and having any percent sequence identity, so long as they have aspartate decarboxylase activity. Applicant discloses a single sequence obtained from *E. coli*. Applicant does not disclose aspartate decarboxylase from any other source. The state of the art does not recognize aspartate decarboxylase from sources other than bacterial. Thus, one skilled in the art cannot make and use unknown and undisclosed aspartate decarboxylase of any percent sequence identity to SEQ ID NO:1 and 2 without undue experimentation.

Claims drawn to sequences having less than 100% sequence identity, including hybridization language, are not enabled because they encompass unspecified base substitutions, deletions, additions, and combinations thereof while retaining aspartate decarboxylase activity. Neither the state of the prior art nor Applicant teaches what region(s) of SEQ ID NO:1 or SEQ ID NO:2 must be retained for the recited activity. The claims encompass inoperable embodiments but the specification provided no guidance as to how such inoperable embodiments can be readily eliminated without undue experimentation. Moreover, while one skilled in the art can readily make mutations to SEQ ID NO:1 or the sequence encoding SEQ ID NO:2, further guidance is needed as to what mutations would not abrogate the recited activity. Applicant provided no working example of any mutant sequences within the 70-90% sequence identity scope which has the recited activity. Accordingly, Applicant has not enabled the less than 100% sequence identity as claimed without undue experimentation.

For all the reasons set forth above, Applicant has not enabled the claimed invention as commensurate in scope with the claims without undue experimentation.

10. Claims 15-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims reciting the generic recitation of aspartate decarboxylase and sequences of less than 100% sequence identity to SEQ ID NO:1 or 2 lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims.

The claims reciting the generic recitation of aspartate decarboxylase and sequences of less than 100% sequence identity, including hybridization language, encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass sequences from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:1 isolated from *E. coli*. No other sources of aspartate decarboxylase are disclosed. No other sequences are disclosed. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and sequences from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate

description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 15-20 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Pompejus et al. (USPN 6696561 (A). It would appear that the enzyme of Applicant is aspartate decarboxylase rather than aspartate carboxylase based upon Applicant's disclosure. Pompejus teaches a plant transformed with a sequence encoding aspartate decarboxylase (col. 28, ln. 26 and Table 2). The plant of Pompejus would inherently possess the properties set forth in claims 16-20. Accordingly, Pompejus anticipated the claimed invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 15-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (J. Bacteriol. 175(7), pp. 2125-2130, 1993 (U)) in view of Goodman et al. (USPN 4956282 (Applicant's IDS)). Jones teaches a sequence which has 100% sequence identity with Applicant's SEQ ID NO:1. Jones identified the sequence as an *E. coli* panB gene encoding a ketopantoate hydroxymethyltransferase, which is identical to Applicant's aspartate decarboxylase.

Jones does not teach plant expression.

Goodman teaches expression of heterologous proteins including enzymes using plants. The protein expressed using the plant system of Goodman would be physiologically active and free from deleterious contaminants. The plant of Goodman can be any of the plants listed in claim 28.

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to express the protein of Jones using the plant system of Goodman as an alternative host for expressing ketopantoate hydroxymethyltransferase (aspartate decarboxylase). The gene of Jones was cloned into an *E. coli* host for sequencing. The state of the art at the time of filling was such that different hosts (bacteria, yeast, plant, mammalian cells, etc.) can be used to express heterologous proteins with relative

ease, as evidenced by Jones and Goodman. The properties set forth in claims 16-20 would be inherent properties of the plant of Goodman expressing the protein of Jones. Accordingly, one would have been motivated to generate the claimed invention without any surprising or unexpected results.

Remarks

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/
Primary Examiner, Art Unit 1638

2/1/08